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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/069,977   | 03/13/2002  | Takakazu Inoue       | 020159              | 2998             |
| 23850  | 7590        | 01/14/2004           | EXAMINER            |                  |
| ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP<br>1725 K STREET, NW<br>SUITE 1000<br>WASHINGTON, DC 20006 |             |                      | TUNG, JOYCE         |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1637                |                  |

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/069,977

Applicant(s)

INOUE, TAKAKAZU

Examiner

Joyce Tung

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: please see the attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 4-9 and 12-16.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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Following the entry of the amendment filed 12/18/2003, the claims 6-9 and 12-16 are pending.

1. The rejection of claims 12-16 under 35 U.S.C. 112, second paragraph is withdrawn.
2. Claims 4-5, 7-9 and 12-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hamad et al. (Journal of Applied Microbiology, 1997, Vol. 83, 764-770), in view of Wilding et al. (5,498,392).

The response filed 12/18/2003 argues that there is no motivation for the modification of the reference to have the "intestinal bacterial flora" limitation, but only an indication of reasonable expectation of success. The indication of reasonable expectation of success is a motivation to apply the method of Hamad et al. to analyzing an intestinal bacterial flora.

The response next argues that Hamad et al. does not provide simultaneous detection of these bacteria, and does not analyze based on the presence or absence of hybridization with a plurality of probes as recited in claim 5. However, the claim language recites "a plurality of probes". It is unclear whether or not there are different DNA probes involved in the plurality of probes.

The response further argues that Wilding's device was not capable of analyzing an intestinal bacterial group as recited in claim 5. Although Wilding et al. do not specifically detect the intestinal bacterial flora, the device of Wilding et al. is a device for PCR including a detector in which the sample is detected (See column 15, lines 11-16). The intestinal bacterial flora is a nucleic acid molecule. Therefore, the device of Wilding et al. is capable of analyzing an intestinal bacterial flora of a subject.

The response additionally argues that Wilding et al. do not disclose using a single device for the analysis and there is no disclosure for use of a plurality of probes on specific position of a

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detector. Since the claim language does not define what is the specific position of a detector. Therefore, the teachings of Hamad et al. in view of Wilding et al. suggest the instant invention. Thus the rejection is maintained.

3. Claim 6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hamad et al. (Journal of Applied Microbiology, 1997, Vol. 83, 764-770) in view of Wilding et al. (5,498,392) as applied to claims 4-5, 7-9 and 12-16 above, and further in view of Mullis et al. (4,800,159). As set forth in section 2 above, with the same reasons, the rejection is maintained.

#### **Summary**

4. No claims are allowable.

5. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

January 9, 2004

*Jeffrey Siew*  
JEFFREY SIEW  
PRIMARY EXAMINER

1/12/04